

### **REMARKS**

The present amendment is submitted in response to an Office Action issued on April 28, 2010.

The application consists of claims 1-4, 6-19. Claims 9-15 are withdrawn from consideration. No amendments to the claims are submitted with the present response.

#### **Specification**

The Examiner objected to the title as being non-descriptive. Applicants have amended the title in the present response to "Ingestible pill for diagnosing a gastrointestinal tract". It is believed that the rejection is overcome by said amendment.

#### **Double patenting**

Claims 1-4, 6, 7 and 16-19 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-9, 60-64, 81, 82, 91, 92, 98, 109-117 and 120-125 of copending application no. 10/240,239 in view of Houzgo (US 6,632,216).

Claims 1 and 16-19 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 40, 46, 48, 49, 58, 64 and 65 of copending application no. 11/132,320 in view of Houzgo.

These rejections are provisional rejections as the conflict claims have not in fact been patented. Applicants will respond to these rejections, if still necessary, when the cited applications will be allowed.

#### **Claim rejections – 35 USC 103**

Claims 1-4, 6-7 and 16-19 stand rejected under 35 U.S.C. 103(a) as being obvious over Hassan et al ("A Radiotelemetry Pill for the Measurement of Ionising Radiation Using a Mercuric Iodide Detector", Phys. Med. Biol., 23(2): 302-308,

1978) in view of Barrett et al (US 4,595,014) and Glukhovsky (US 6,584,348) and further in view of Schentag (US 5,279,607).

Applicants respectfully disagree with the rejection and submit that the Examiner did not provide a *prima facie* case of obviousness since the prior art fails to teach all of the claimed features.

The cited art fails to teach "circuitry comprising at least one sensor adapted to determine the location and orientation of the ingestible device in the gastrointestinal tract and the circuitry is further adapted to reconstruct the diagnostic image based on said location and orientation" of claim 1

In the office action, page 6, the Examiner states that Hassan, Barrett, Glukhovsky and Schentag fail to teach the system comprising circuitry adapted to determine the orientation of the ingestible device. However, the Examiner further asserts that Hassan does suggest the need for orienting the ingestible device on page 306, first paragraph under Performance section. Accordingly, the Examiner concludes that it would have been obvious for a person of ordinary skill in the art to modify Hassan, Barrett, Schentag and Glukhovsky to include circuitry capable of sensing the orientation of the ingestible device. Applicants respectfully disagree and submit that Hassan does not provide any motivation for orienting the ingestible device.

Following is a quotation of the indicated paragraph in Hassan:

**To make a preliminary evaluation of the radiopill, tests were carried out in air and water tanks in order to simulate the use of the pill *in vivo*. Measurements permitted the determination of the polar diagram, temperature dependence and sensitivity to several radioactive sources. Fig. 4 shows the polar diagram response of the radiopill using a 1 mm radius 'point source' of 1.7 mCi <sup>99m</sup>Tc. It is seen that the polar diagram is fairly isotropic except on the battery side which shields some of the incoming radiation. Similar results are shown for a**

In this paragraph Hassan mentions that the battery side shields some of the incoming radiation. The Examiner concludes therefrom that it would have been

obvious for a person of ordinary skill in the art to modify Hassan, Barrett, Schentag and Glukhovsky to include circuitry capable of sensing the orientation of the ingestible device in order to improve detection of radiation by the pill when the source is angled behind the battery side of the detector.

Applicants respectfully disagree with this conclusion and submit that **knowing the orientation of the ingestible device *would not* improve the detection of Hassan**. Even if Hassan would know the exact orientation of the ingestible device, Hassan would still not know the direction from which the detected radiation is sensed from and would therefore not know if the battery shielded some of the incoming radiation. Accordingly, Hassan would have no reason for adding circuitry comprising at least one sensor adapted to determine the location and orientation of the ingestible device in the gastrointestinal tract as recited in claim 1.

The cited art fails to teach "*wherein said ingestible device comprises a plurality of nuclear-radiation detectors, arranged around said probe*" of claim 1.

On page 5 of the office action, the Examiner states that Hassan does not disclose an ingestible device with a plurality of nuclear radiation detectors arranged around the external surface of the ingestible device. However, Barrett teaches a nuclear radiation probe that includes multiple radiation detectors. Accordingly, the Examiner submits that it would have been obvious to a person of ordinary skill in the art to modify Hassan to create an ingestible device with a plurality of radiation detectors. Applicants respectfully disagree.

Barrett describes an endoscope having a plurality of nuclear radiation detectors, where the location and orientation of the endoscope is known. In Barrett, the multiplicity of radiation detectors serves for eliminating the need of rotating the endoscope and/or collimator, see col. 3, lines 62-67.

Applicants submit that endoscopes have different challenges than ingestible devices as recited in claim 1 and therefore a person of ordinary skill in the art would not find it obvious to combine the plurality of detectors from Barrett's endoscope to Hassan's ingestible device. For example, in an ingestible device, the orientation and rotation of the device is practically not controllable. Thus, the motivation for Barrett to provide a plurality of detectors to his endoscope is simply not present in Hassan. Accordingly, a person of ordinary skill in the art, reading Barrett, would not add a plurality of detectors to Hassan's pill.

The Examiner further cites Glukhovsky which teaches a capsule with electrode probes protruding out from the openings of the capsule and states that it would have been obvious to a person of ordinary skill in the art to modify Hassan in view of Barrett to include a plurality of nuclear radiation detectors arranged around the external surface of the ingestible device. According to the Examiner, such a modification would improve the sensitivity of the probes by not enclosing them by an encapsulation that could potentially attenuate the detectable radiation.

Applicants respectfully disagree. Glukhovsky is measuring electrical characteristics (and not nuclear radiation!) for which multiple electrodes are necessary.

Electrical detection includes different engineering challenges and different modulation than radiation detectors. For example, radiation detection is volumetric, while electrical detection is not even surface size dependent up to some limit. Therefore, reducing the size of electrical detectors generally increases the sensitivity of the detectors. While reducing the size of a radiation detector reduces the sensitivity of the detector and increases the noise thereof.

In addition, in order to measure electric characteristics of a tissue as done by Glukhovsky, a minimum of four electrodes are needed (Col. 5, lines 15-16). Thus, a person of ordinary skill in the art would have no other choice than to use at least four electrodes for this electrical characterization. However, since one radiation detector is enough for measuring radiation characteristics of a tissue, a person of ordinary skill in the art would use only a single radiation detector in an ingestible device where the size and modulation challenges are severe.

In view of the major differences and engineering challenges, a man of ordinary skill in the art would have been taught against applying any methodology used for electrical detection to radiation detection and would not combine Glukhovsky with Hassan or Barrett.

Accordingly, it is submitted that claims 1-4, 6 and 7 are patentable over the art. It is further submitted that claim 16 includes similar features of a plurality of nuclear radiation detectors and determining the location and orientation of the ingestible device. Accordingly, claim 16 is also believed to be patentable over the cited art.

### **Conclusion**

In view of the above remarks, applicant submits that the claims are patentable over the prior art. Allowance of the application is respectfully awaited.

Respectfully submitted,

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